Additional Remarks by Government Senators

Part 1 - GENERAL REMARKS

1. Government Senators welcome the decision of the Committee to recommend that the Senate agree to the Australia-US Free Trade Agreement Implementation Bill. The passage by the Senate of the Bill will clear the last hurdle remaining before the Australia-US Free Trade Agreement ("FTA") can come into effect on 1 January 2005.

2. The overwhelming weight of credible evidence received by the Committee supports the view that the FTA will be of significant benefit to the Australian economy in the short, medium and long term. It gives Australia unparalleled access to the largest market in the world. It strengthens the bonds between the Australian economy and the world's most dynamic economy.

3. From the first day of the FTA, 97% of US non-agricultural tariffs (with the exception of textiles and clothing) will disappear. Other non-agricultural tariffs will be phased out by 2015. From the first day of the FTA, two thirds of agricultural tariffs will disappear. A further 9% of agricultural tariffs will be phased out by 2009, and others by 2016. Australian firms will have unparalleled access to the $US200 billion government procurement market. According to some witnesses, about 60% of the economic benefits of the agreement will be felt in the field of investment, as the synergies between the two economies strengthen.

4. It cannot be said too plainly that, where there has been criticism of the agreement, much of the disagreement has been about the *extent of the benefits*. The most pessimistic assessment of the agreement, by Dr. Phillipa Dee, estimated the benefits at only $53 million per annum. The Government's own modelling consultant, the Centre for International Economics, assessed the benefits at $6 billion per annum. Most econometricians agreed, however, that the "dynamic effects" of the agreement were difficult to quantify, since its real benefits will only be seen in its operation. The Committee heard evidence that the North American Free Trade Agreement had, in the first decade of its operation, achieved benefits which were a multiple of those initially predicted.

5. One of the most impressive witnesses the Committee heard from was Mr. Alan Oxley, former Australian Ambassador to the GATT, and one of Australia's most distinguished trade experts, who (unlike some academic

witnesses) has actual "hands on" experience of the operation of trade agreements. Mr. Oxley told the Committee in his evidence on May 5:

> "You asked, Chair, what would be the downside for Australia if we rejected the agreement. We would probably be regarded as the most bizarre country in the world for having rejected a free trade agreement with the world's biggest economy … an agreement that would give us access in agriculture, which is one of the most difficult areas, notwithstanding the fact that it is not perfect – when many other countries are lining up to have an agreement with them. I honestly do not know how any serious Australian government could justify that to the world at large."

6. While Government Senators accept that the Chairman's Report contains a reasonably balanced canvass of the evidence, we are nevertheless dissatisfied with the approach taken in expressing conclusions. The approach has been to adopt, almost *in terrorem*, warnings based upon the law of unintended consequences. Typical is paragraph 4.140, concerning pharmaceuticals and the PBS:

> "What most concerns this committee is the possibility that allowing Australia's pharmaceutical policies and IP laws to be up for grabs in this agreement could have unforeseen and unintended consequences down the track. This report has repeatedly noted that the FTA is in a sense a living agreement. Further work will take place in forums such as the working groups set up under it. Many of the details of what it means and how it will be implemented will be sorted out later, possibly with the help of the dispute-resolution mechanism. While we understand the Australian negotiators' interpretation of the agreement, we cannot predict the actions of the US or the dispute resolution mechanism into the future."

7. That passage (which is typical of so much of the Chairman's draft) reads as if it were written so as to avoid coming to a conclusion. Yet the task of the Committee *is* to reach conclusions, and Government Senators note with satisfaction that, in the end, Opposition Senators have concurred with the Government in supporting the FTA. But it should not go unnoticed that the Report gives relatively uncritical ventilation to a large number of criticisms of the FTA by special interest groups (particularly, although not exclusively, from the trade union movement), together with disappointingly unscholarly ideological polemics by certain academics claiming for themselves an expertise which they plainly lacked, without making the obvious point that those criticisms were answered comprehensively and in detail by those who possessed genuine expertise and detailed knowledge about the working of the Agreement, in particular the Chief Negotiator, Mr. Stephen Deady, and his team, who gave the Committee an abundance of their time, and were able to answer such criticisms painstakingly, thoroughly and in detail. Government Senators refer, in particular, to that evidence during the long sessions on 21 June and 6 July, when those witnesses were taken carefully through each of the contentious areas.

8. Most of the concerns raised about the agreement, when scrutinized, amount to nothing more than a failure to understand the language of the FTA (or, in the case of some witnesses, it must be said, failure even to read the relevant sections before essaying criticisms, or a stubborn refusal to allow the technical meaning of the language to be explained to them). The FTA is a long and complex legal document, proper understanding of which requires a level of knowledge of international trade law and the law of treaties. Informed debate about it is inevitably of a somewhat technical character. Nevertheless, if the task of the Committee is to assess the document, it must first understand it. In reaching that understanding, heated emotional polemics, reflexive anti-Americanism, ideological rants and fanciful conspiracy theories are of absolutely no assistance, and bear little weight beside the dry, methodical, erudite technical explanations of Mr. Deady and his team. When those responses are considered, it will be perfectly apparent that the concerns raised by various critics are not based on an understanding of what the Agreement actually says. In our discussion of the effect of the agreement on generic pharmaceuticals which follows, we draw extensively upon Mr. Deady's evidence, the clarity and authority of which speaks for itself.

9. The Joint Standing Committee on Treaties reviewed the Agreement in Report No. 61, tabled in the Senate on 23 June 2004. Government Senators adopt the conclusions expressed by JSCOT, whose Report, it must be said, has reflected a more analytical approach to the Treaty than the Chairman's Report of this Committee.

10. Government Senators are clearly satisfied that the FTA is overwhelmingly in the national interest; a view they share with all of the State Premiers and virtually the entirety of the Australian business community. They welcome the decision of the Opposition to support the FTA. The Agreement may not be perfect – and it was never represented to be – but it will, we are satisfied, be viewed by future generations as an historic foundation of our nation's growing economic prosperity in the 21st century.

Part 2 - GENERIC PHARMACEUTICALS

1. At the time these remarks were prepared, there remained one outstanding issue between the Government and the Opposition delaying passage of the enabling legislation through the Senate, i.e. the possible effect upon the market for generic pharmaceuticals in Australia of Art. 17.10.4, which is given effect to by Schedule 7 of the *US Free Trade Implementation Bill* ("the *FTA Bill*"). Government Senators are satisfied that those concerns are misplaced, for the reasons set out below.

2. Labor Senators argue that the effect of the FTA will be to delay the entry of generic drugs onto the market. In doing so, they rely upon the evidence summarized at paragraphs 4.75 – 4.108 of the Chairman's Report. Government Senators consider that the position of Labor Senators is based on a misunderstanding of the effect of Art. 17.10.4 and of Schedule 7 of the *FTA Bill*.

3. Generic drugs are pharmaceuticals which are no longer patent-protected. Evidence given to the Committee estimated that the price of such drugs is on average about 30% below that of patent-protected medicines. Patent protection of pharmaceuticals lasts for 20 years. The Committee heard evidence that the patent protection of a significant number of pharmaceuticals will expire within the next 5 years, including important anti-cholesterol drugs and antidepressants. Any delay in the opportunity for generic drugs to be marketed in Australia would, so the argument goes, prevent access to the cheaper generic drugs at an earlier time, so maintaining higher pharmaceutical prices.

4. The Committee heard evidence that in the United States and Canada, pharmaceutical companies have sought to extend the life of their patents (and thus their monopoly on the particular drug) by lodging applications to extend patents, shortly before their expiry, on insubstantial grounds, or by patenting allegedly "new" drugs which are not materially different from the existing drug (and thereby not properly patentable) and, on the basis of the newly-patented drug, challenging the generic drug as an infringement of the new patent. Under the American legislation, the *Hatch-Waxman Act*, there is an automatic 30 month injunction against the generic drug (and under Canadian law, 24 months) when this happens. During that period (or any longer time during which its claim is litigated), the original patent-holder can continue to enjoy monopoly profits as the sole supplier of the drug; if its challenge is unsuccessful, the costs of the litigation are likely to be minute in comparison to the profits earned in the meantime. Further, it can then file a further patent, triggering the statutory injunction for a new period, and repeat the process. These practices – which are in truth an abuse of process - are colloquially called "evergreening". The evidence was conflicting as to just how extensive the practice of evergreening in the United States is. One witness, Dr. Thomas Faunce, asserted that the practice affects some 53% of American pharmaceuticals coming off patent, although Mr. Deady was of the view that the figure was closer to 6%.[1] In any event there is no doubt that the practice exists.

5. Labor Senators claim that Article 17.10.4 of the FTA (to which effect is given by Schedule 7 of the *FTA Implementation Bill*, which amends s. 26 of the *Therapeutic Goods Act*), is an evergreening provision, and for the reasons explained above, will place upward pressure on Australian

1 Hansard 21 June 2004 pp. 25 & 48 respectively.

pharmaceuticals by giving the manufacturers a legal device to prevent generics coming onto the market (or at least delay the effect of downward price pressures resulting from the introduction of the cheaper generics).

6. That argument is wrong, for several reasons:

(a) The proposed amendments *do not* provide for a statutory injunction, unlike American and Canadian law. Labor's claims that the FTA would introduce American-style registration procedures into Australian law are untrue. In fact, as Mr Deady, said in his evidence to the Committee on 21 June, Art. 17.10.4 was the outcome of successful negotiation by the Australian negotiators to achieve the *very outcome* that Australian pharmaceutical process would not be affected by any process similar to the American one: *Hansard* pp. 33-34, which we set out at length in paragraph 7 below. He specifically and emphatically rejected the characterisation of Art. 17.10.4 as an evergreening provision.

(b) The amendments to Australian domestic law do not alter the existing rights of patent-holders. If the owner of a patent decides to sue the manufacturer of a generic drug for infringement of its patent, then there is nothing to stop it doing so. The material difference between Australian & US law is, as explained above, there is no automatic right to a statutory injunction, nor a minimum period if an injunction were to be granted. In short, *Australian patent law, and the Australian law governing the principles on which injunctions are granted, do not change*.

(c) Art. 17.10.4 and Schedule 7 of the *FTA Bill* are not laws which extend the intellectual property rights of patent holders. They are laws about the approval procedure for the listing of generic pharmaceuticals by the Therapeutic Goods Administration under the *Therapeutic Goods Act.* They effect one change to the procedure for the granting of TGA approval. This is to introduce a requirement that an applicant for approval of a generic drug certify to the TGA *either* (a) that it does not propose to market the generic drug in a manner which would infringe an existing patent. [s. 26B(1)(a)] *or*, if it does propose to market the generic drug before the patent term expires, it has given the patent holder notice of that fact [s. 26B(1)(b)]. However, this is merely a *procedural step in the approval process*: it merely requires the certification of something. It does not give the TGA the right to delay the application, nor does it introduce any additional criterion for the TGA to consider in determining the application. The amendments to the *Therapeutic Goods Act* make that perfectly clear, because by the *FTA Bill* the *Therapeutic Goods Act* is also amended to say that, if the certificate is supplied under s. 26B(1), "the Secretary *must* list the medicine

under subsection (1) without inquiring into the correctness of the certificate" (emphasis added).

(d) The lodgement of the certificate neither involves delay (it is just one additional piece of paper), nor does it give the TGA any power to delay the listing (if the other existing criteria are satisfied). The only difference is that the patent holder is notified. The patent holder could then bring patent infringement proceedings, *but it has that right already*. The only practical change is that a patentee which has received a notice under s. 26B(1)(b)(iii) and decides to bring proceedings for an injunction to restrain infringement of its patent, is likely to bring those proceedings at an earlier time. Yet that in fact benefits the supplier of the generic pharmaceutical: if its right to market the drug is to be challenged on the basis of patent infringement, then better that dispute be had early, before the costs of manufacturing, distributing and marketing the generic drug have been incurred than afterwards. That is not to say that the patent holder might not seek to enforce an unmeritorious claim by one of the evergreening devices. But it can already do that under the existing law; as we have already pointed out, the amendments to the *Therapeutic Goods Act* do not alter the substantive law of patents. In particular, they do not introduce the statutory injunction procedure provided for by American law.

7. Mr. Deady's evidence on these matters was unambiguous and emphatic:

> "Claims … that these changes will delay generics entering the market, therefore pushing up the price of the PBS – again, I will say this as clearly as I can – are not true. There is no change to patent terms in article 17.10.4, or anywhere in the IP chapter.
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> …
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> "There is nothing that affects the patent terms or any possibility of extension of test data. There is one change, as I said, to the TGA, which people will see tomorrow [*scil.* Schedule 7 of the *FTA Bill*], to give effect to the commitments on 17.10.4. These measures that are part of these commitments that we have given relate to introducing measures in the marketing approval process which will prevent the marketing of drugs that are currently under patent. That is the existing law in Australia: drugs that are under patent cannot be marketed on the Australian market. So there will be some changes there to give effect to the measures in the marketing approval process but they will not delay generic drugs onto the market."[2]
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> "We are not importing the Hatch-Waxman legislation into Australian law as a result of the free trade agreement. So I really do think that comments about

2 Hansard 21 June 2004 p. 16

30-month stays or 24-month stays are not relevant to the commitments we have made to the United States and how we are going to give those effect in legislation. On the specifics of provision 17.10.4, I say again that that was a very tough negotiation. … we did speak long and hard to the generics industry.

"We understood their concerns in this area and we have negotiated an outcome which we believe meets those concerns. It does provide the ongoing balance between the interests of the generic medicines industry and the legitimate rights of patent holders in these areas. That is what we have negotiated. That is what the language reflects. It says that we will provide measures in the marketing approval process to prevent persons from marketing their product where the product is claimed under a patent. That is what we have given effect to, and that is what we will be giving effect to in legislation. We believe that does not give any new rights to patent holders, but it does establish an addition step in the TGA in the marketing approval process.

…

The TGA will be required, as part of the marketing approval process, to establish an additional step to ensure that the generic seeking marketing approval is not intending to market that drug during the patent term. That is the additional procedural step that will be required. It does not add an additional patent right to the patent holder, but it does establish an additional step in that marketing approval process. That is what we are committed to under 17.10.4

Senator BRANDIS – When you say 'an additional step', is there a minimum time for compliance with that additional step? Because it is being said against you here by Dr. Lokuge and Dr Faunce that this will spin things out for 24 months, or at least for a prolonged period of time. As I understand it, you said that that is just wrong. Why does the additional step not involve any delay?

Mr. Deady – It certainly does not involve any delay. It is an additional administrative question, or certification, that will be asked of the generics when they are seeking marketing approval. It will not in any way delay the normal marketing approval processes. There is no timing issue.

Senator BRANDIS – No timing issue at all?

Mr. Deady – No. … It will not extend the time of the marketing approval process, and it does not add or provide any additional rights to the patent holders in that process. … That is the basis on which we negotiated this language.

Senator BRANDIS – And that is why you negotiated this language, to ensure that that did not happen?

Mr. Deady – To ensure there would not and could not be such a delay.

…

> **Senator BRANDIS** – So 17.10.4, in the form which it now takes in its ultimate expression in the final draft, was in fact – do I understand you to be saying – the product of the Australian side successfully negotiating to avoid the very thing which Dr Lokuge has expressed concern about?
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> **Mr. Deady** – Yes, to ensure that there would not be any way through any aspect of the FTA, including the IP area, where the fundamentals of the PBS could be impacted. That was what we were negotiating about, and that is what we achieved through that language.[3]

8. Dr. Ruth Lopert, the witness from the Pharmaceutical Benefits Branch of the Department of Health and Ageing, agreed with Mr. Deady:

> "Dr. Faunce … suggested that article 17.10 part 4 was a provision that would allow evergreening of patents. I would strongly argue that the evergreening of patents is something which is not either provided for or supported by any of the provisions of this agreement. The evergreening of patents is something that will be pursued where pharmaceutical companies believe it is in their interests to do so. There is nothing in this text which either supports or impedes that. There is nothing in 17.10.4 that promotes the evergreening of patents."[4]

According to Mr. Deady, Art. 17.10.4 actually represented a *win* for the Australian negotiators, by keeping the Australian listing procedures unaffected by the American system:

> [T]hese are things that the United States pressed us about. These are things that they did want as part of these negotiations. We had a lot of discussion with the generic industry leading into the process and right through the process. They were areas of concern. Those concerns have been fully addressed. … We specifically did not agree to have 30-month or 24-month stays. Again, this is something I think the American would certainly have liked us to have agreed to as part of these negotiations. We did not agree with those points."[5]

9. Indeed, even the principal witness criticizing the operation of Art. 17.10.4, Dr. Lokuge (whose testimony, in Government Senators' view, was considered and dispassionate), conceded that if Mr. Deady's explanation was correct, his concerns were unfounded:

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3 Hansard 21 June 2004 pp. 31-4

4 Hansard 21 June 2004 p. 18

5 Hansard 21 June 2004 p. 16

> **Senator BRANDIS** – Dr. Lokuge, I listend to what you said … I heard you calling our attention to the criticisms of the Generic Medicines Association as to the possible impact of 17.10.4. We have also heard from Mr. Deady. It's as simple as this, Dr. Lokuge: if Mr. Deady is right about what 17.10.4 means and you are wrong about it, then your argument completely collapses, and you do not have a complaint?
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> **Dr. Lokuge** – That is right.[6]

The reliability of the evidence of Dr. Faunce, the other principal critic of Art. 17.10.4, as well as his entitlement to be regarded as an objective expert, must be judged in light of the evident motive which underlay his "analysis", which was eventually exposed as his testimony before the Committee degenerated into an ideological rant:

> **Dr. Faunce –** If Australia stands up at this moment in its history and makes a decision that it is not going to go down the path of signing this unbalanced agreement which trades off its unique public health and social justice imperatives, it will deserve to become a republic. It will deserve to have a strong and independent voice on the international stage. If we do not do that and we roll over and become the poodle of the United States on this, as we are on so many other human rights initiatives, then we do not deserve to become a republic.[7]

10. In light of the foregoing analysis, and the considered and reassuring expert evidence given to the Committee by Mr. Deady which we have set out, Government Senators consider concerns about the effect of article 17.10.4 of the FTA and the implementing legislation to be without substance. They certainly provide no justification for refusal to take advantage of such an overwhelmingly beneficial agreement.

Senator George Brandis
Deputy Chairman

Senator Jeannie Ferris

Senator Ron Boswell

4 August 2004

6 Hansard 21 June 2004 p. 32

7 Hansard 21 June 2004 p. 57